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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,269	02/20/2001	Kensaku Imai	826.1335C	2896

21171 7590 07/19/2002

STAAS & HALSEY LLP
700 11TH STREET, NW
SUITE 500
WASHINGTON, DC 20001

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/19/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,269	IMAI ET AL.	
	Examiner	Art Unit	
	John S Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-26 and 28-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-26 and 28-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Specification

1. The request to use the Computer Readable Form of the Sequence Listing of parent application No. 08/684674 filed with the instant application has been entered. The applicants are requested to explicitly invoke 37 CFR 1.821(e) as discussed in MPEP 2422.05 in the future when making such requests.
2. The first preliminary amendment filed 20 February 2001 required renumbering of claims and dependencies as noted in the supplemental amendment filed 24 May 2001. This Office action reflects the renumbering of the claims.
3. Comments regarding a prior Office action in the first preliminary amendment filed 20 February 2001 have not been considered because the instant application does not have a prior Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 23-26 and 28-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-26 and 28-31 are indefinite for recitation in the final line of claim 23 “removing nucleic acid molecules of the vector at the specified junction” because the method steps and the preamble define an invention that manipulates sequence data rather than polynucleotides, while the above phrase refers to polynucleotide molecules. The rejection would

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be overcome by amending claim 23 to recite “removing base sequence data of the vector at the specified junction.”

Claims 29 and 31 are indefinite because it is not clear what is meant by the phrase “when the area specified by the second homology retrieval is one.”

Claims 32-40 are indefinite for recitation of the phrase in lines 1-2 “A device for removing nucleic acid molecules of a vector from a recombinant DNA base sequence” because the claim is drawn to a method of analysis of sequence data rather than polynucleotides. The rejection would be overcome by amending claim 32 to recite “A device for removing base sequence data of a vector sequence from a recombinant DNA base sequence.”

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 23, 32, 34-38 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (reference AK in the Form PTO 1449 filed 5/27/97)

The claims are drawn to a method of removing vector sequences from DNA sequence data by a process of identifying known vector sequences at the beginning and the end of the insert sequence of interest in the DNA sequence data and removing the identified vector sequences. In some embodiments the claims are further limited to removing vector sequences that meet or exceed a similarity threshold, to an apparatus that performs the method, and to a storage medium comprising a computer program that removes vector sequences from DNA

sequence data by a process of identifying known vector sequences at the beginning and the end of the insert sequence of interest in the DNA sequence data and removing the identified vector sequences.

Smith et al. describe a computer-implemented method for removing vector sequences from DNA sequence data by a process of identifying known vector sequences at the beginning and the end of the insert sequence of interest in the DNA sequence data and removing the identified vector sequences. On page 1015, Smith et al. characterize their method and apparatus as follows:

"Prior to assembly, the raw sequences can be checked for the presence of a vector sequence that could adversely affect the assembly. The vector sequences can be manually entered or imported from a file on a hard or a floppy disk. The user then establishes the percentage of bases in the cloning vector sequence that must match the bases at the head or the tail of a fragment sequence to designate a cloning vector. Sequence regions matching the cloning vector at, or above, the specified percentage are automatically removed from the raw sequence."

Therefore, Smith et al. anticipates the claimed invention. Regarding language in the claims concerning restriction enzyme site detection and storage, such detection and storage is inherent in detection and storage of vector sequences because the vector sequences designated to be deleted comprise restriction enzyme sites.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (reference AK in the Form PTO 1449 filed 5/27/97).

The claims are drawn to a method of removing vector sequences from DNA sequence data by a process of identifying known vector sequences at the beginning and the end of the insert sequence of interest in the DNA sequence data and removing the identified vector sequences that is further limited to comprise a display means that displays the vector sequence.

Smith et al. describe a computer-implemented method for removing vector sequences from DNA sequence data by a process of identifying known vector sequences at the beginning and the end of the insert sequence of interest in the DNA sequence data and removing the

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"Prior to assembly, the raw sequences can be checked for the presence of a vector sequence that could adversely affect the assembly. The vector sequences can be manually entered or imported from a file on a hard or a floppy disk. The user then establishes the percentage of bases in the cloning vector sequence that must match the bases at the head or the tail of a fragment sequence to designate a cloning vector. Sequence regions matching the cloning vector at, or above, the specified percentage are automatically removed from the raw sequence."

Smith et al. shows in figure 1 a visual display produced by their apparatus. Smith et al. does not show display means that displays the vector sequences.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Smith et al. by use of a display means to display the vector sequences to aid in choosing the vector sequences that are to be used in the method.

Allowable Subject Matter

10. Claims 24-26, 28-31, 39, and 40 would be objected to as being dependent upon a rejected base claim if the above rejection under 35 U.S.C. § 112, second paragraph were overcome, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims recite the limitation of a repetition of detection of a junction sequence in base sequence data.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M_F 8:30-5:00.

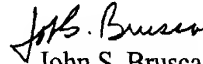
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb
July 12, 2002